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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of Antonio J. Grillo-Lopez et al.	Examiner: Quang Nguyen
Serial No. 09/613,038	Docket No.: 22338-602
Filed: July 10, 2000	Group Art Unit: 1636
For: BLOCKING IMMUNE RESPONSE TO A GRAFT (Amended)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

Listed on the accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that an exhaustive search has been made, or that there does not exist information more material to the examination of the present patent application. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will review art of record in all 35 U.S.C. § 120 priority documents.

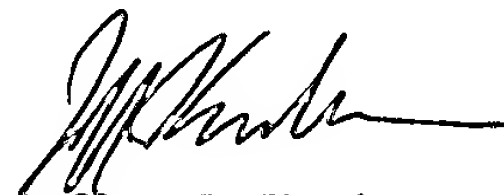
1. ☒ The Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of an Office Action.
 - a) ☒ We authorize the deduction of \$180.00 from Deposit Account 18-1260 in payment of the fee under 37 C.F.R. § 1.17(p).

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- b) It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449 documents, and to indicate in the official file wrapper of this patent application that these documents have been considered.

Respectfully submitted,



Jeffrey P. Kushan
Reg. No. 43,401
Attorney for Applicants

SIDLEY AUSTIN BROWN & WOOD LLP
1501 K Street, N.W.
Washington, D.C. 20005
(202) 736-8000

Dated: January 28, 2005

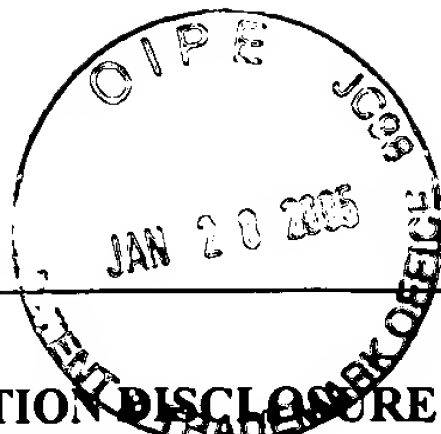


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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

199	Aggarwal A, et al., Rituximab: an anti-CD20 antibody for the treatment of chronic refractory immune thrombocytopenic purpura, South Med J. 2002 Oct;95(10):1209-12
200	Anderson D, et al., A Primatized MAb to Human CD4 Causes Receptor Modulation, without Marked Reduction in CD4 ⁺ T Cells in Chimpanzees: <i>In Vitro</i> and <i>in Vivo</i> Characterization of a MAb (IDEC-CE9.1) to Human CD4, Clinical Immunology and Immunopathology, Vol. 84, No. 1, July, pp 73-84, 1997, Article No. II974363
201	Anolik JH, et al., Rituximab improves peripheral B cell abnormalities in human systemic lupus erythematosus, Arthritis Rheum. 2004 Nov;50(11):3580-90
202	Arzoo K, et al., Treatment of refractory antibody mediated autoimmune disorders with an anti-CD20 monoclonal antibody (rituximab), Ann Rheum Dis 2002;61:922-924
203	Berrih S, et al., Interferon-gamma modulates HLA class II antigen expression on cultured human thymic epithelial cells, J Immunol. 1985 Aug;135(2):1165-71
204	Berentsen S, et al., Rituximab for primary chronic cold agglutinin disease: a prospective study of 37 courses of therapy in 27 patients, Blood. 2004 Apr 15;103(8):2925-8
205	Bonilla FA, et al., Primary immunodeficiency diseases, J Allergy Clin Immunol. 2003 Feb;111(2 Suppl):S571-81
206	Buckley CD, Treatment of rheumatoid arthritis, BMJ Volume 315, 26 July 1997, pp 236-238
207	Buckley RH, Primary cellular immunodeficiencies, J Allergy Clin Immunol. 2002 May;109(5):747-57
208	Bujiah J, et al., Detection of class II antigens on human nasal cartilage, Am J Otolaryngol. 1990 Sep-Oct; 11(5):339-44
209	Choy EHS, et al., Cytokine Pathways and Joint Inflammation in Rheumatoid Arthritis, N Engl J Med, Vol. 344, No. 12, March 22, 2001, pp 907-915
210	Choy EHS, et al., Repeat-cycle study of high-dose intravenous 4162W94 anti-CD4 humanized monoclonal antibody in rheumatoid arthritis. A randomized placebo-controlled trial, Rheumatology 2002;41:1142-1148
211	Coll AP, et al., Rituximab therapy for the type B syndrome of severe insulin resistance, N Engl J Med. 2004 Jan 15;350(3):310-1
212	Cragg MS, et al., Antibody specificity controls in vivo effector mechanisms of anti-CD20 reagents, Blood, 1 April 2004, Volume 103, Number 7, pp 2738-2743
213	DeNardo GL, et al., Characterization of Human IgG Antimouse Antibody in Patients with B-Cell Malignancies, Clinical Cancer Research, Vol. 9, 4013s-4021s, September 1, 2003 (Suppl.)

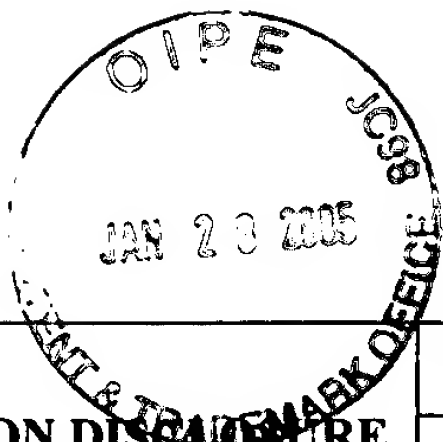
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Form PTO-A820 (also form PTO-1449)	SHEET 1 OF 6



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214	Dupuy A, et al., Treatment of refractory pemphigus vulgaris with rituximab (anti-Cd20 monoclonal antibody), Arch Dermatol. 2004 Jan;140(1):91-6
215	Edwards JCW, et al., Rheumatoid Arthritis: The Predictable Effect of Small Immune Complexes In Which Antibody Is Also Antigen, British Journal of Rheumatology 1998;37:126-130
216	Edwards JCW, et al., Do self-perpetuating B lymphocytes drive human autoimmune disease?, Immunology 1999;97:188-196
217	Edwards JCW, et al., Efficacy of B-Cell-Targeted Therapy with Rituximab in Patients with Rheumatoid Arthritis, The New England Journal of Medicine, June 17, 2004; 350:2572-71
218	Endo T, et al., Successful treatment with rituximab for autoimmune hemolytic anemia concomitant with proliferaton of Epstein-Barr virus and monoclonal gammopathy in a post-nonmyeloablative stem cell transplant patient, Ann Hematol. 2004 Feb;83(2):114-6
219	Espana A, et al., Long-term complete remission of severe pemphigus vulgaris with monoclonal anti-CD20 antibody therapy and immunophenotype correlations, J Am Acad Dermatol. 2004 Jun;50(6):974-6
220	Gajra A, et al., Response of myasthenia gravis to rituximab in a patient with non-Hodgkin lymphoma, Am H. Hematol. 2004 Oct;77(2):196-7
221	Geha RS, Antibody deficiency syndromes and novel immunodeficiencies, Pediatr Infect Dis J. 1988 May;7(5 Suppl):S57-60
222	Goebeler M, et al., Rapid response for treatment-resistant pemphigus foliaceus to the anti-CD20 antibody rituximab, Br J Dermaol. 2003 Oct;149(4):899-901
223	Graus F, et al., Complex antigens in normal human dorsal root ganglia, J Neurol Sci. 1990 Sep;98(2-3):203-11
224	Harner KC, et al., Normalization of anticardiolipin antibodies following rituximab therapy for marginal zone lymphoma in a patient with Sjorgen's syndrome, Rheumatology (Oxford), 2004 Oct;43(10):1309-10
225	Heath M, et al., Evidence-based evaluation of immunology therapy for the cutaneous manifestations of lupus, Adv Dermatol. 2004;20:257-91
226	Hepburn TW, et al., Antibody-medicated stripping of CD4 from lymphocyte cell surface in patients with rheumatoid arthritis, Rheumatology 2003;42:544-61
227	Jonasson L, et al., Expression of class II transplantation antigen on vascular smooth muscle cells in human atherosclerosis, J Clin Invest. 1985 Jul;76(1):125-31

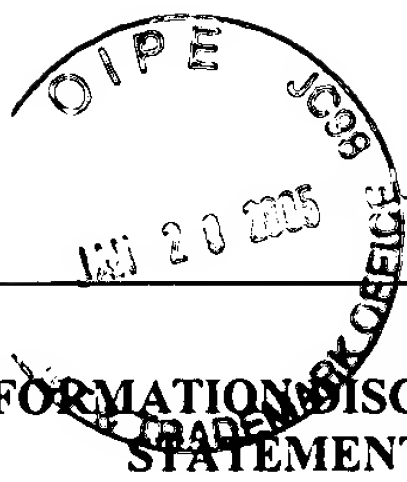
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228	Kawai T, et al., Thromboembolic complications after treatment with monoclonal antibody against CD40 ligand, February 2000, Volume 6, Number 2, pp 1-4
229	Kazkaz H, et al., Anti B cell therapy (rituximab) in the treatment of autoimmune diseases, Curr Opin Pharmacol. 2004 Aug;4(4):398-402
230	Kinn SR, et al., Detection and quantation of HLA class II molecules on keratinocytes by quantitative immunofluorescence, J Immunol. Methods. 1990 Dec 5; 134(2):243-51
231	Kon OM, et al., The effects of an anti-CD4 monoclonal antibody, keliximab, on peripheral blood CD4+T-cells in asthma. Eur Respir J 2001; 18:45-52
232	Laguens G, et al., Demonstration and characterization of HLA-DR positive cells in the stroma of human endometrium, J Reprod Immunol. 1990 Sep;18(2):179-86
233	Levy O, et al., Results of a Placebo-Controlled, Multicenter Trial Using a Primatized® Non-Depleting, Anti-CD4 Monoclonal Antibody in the Treatment of Rheumatoid Arthritis, American College of Rheumatology, Volume 39, No. 9 (Supplement) September 1996
234	Lloyd RV, et al., Detection of HLA-DR antigens in paraffin-embedded thyroid epithelial cells with a monoclonal antibody, AM J Pathol. 1985 Jul;120(1):106-11
235	Looney RJ, Treating human autoimmune disease by depleting B cells, Ann Rheum Dis 2002;61:863-866
236	Looney RJ, et al., B cell depletion as a novel treatment for systemic lupus erythematosus: a phase I/II dose-escalation trial of rituximab, Arthritis Rheum. 2004 Aug;50(8):2580-9
237	Looney RJ, et al., B cells as therapeutic targets for rheumatic diseases, Current Opinion in Rheumatology 2004, 16:180-185
238	Maloney DC, et al., IDEC-C2B8 (Rituximab) Anti-CD20 Monoclonal Antibody Therapy in Patients with Relapsed Low-Grade Non-Hodgkin's Lymphoma, Blood, Vol 90, No 6, Sept. 15, 1997: pp 2188-2195
239	Mavragani CP, et al., A case of reversible posterior leucoencephalopathy syndrome after rituximab infusion, Rheumatology (Oxford). 2004 Nov;43(11):1450-1
240	Moreland L, et al., Double-blind, Placebo-Controlled Multicenter Trial Using Chimeric Monoclonal Anti-CD4 Antibody, cM-T412, in Rheumatoid Arthritis Patients Receiving Concomitant Methotrexate, Arthritis & Rheumatism, Vol. 38, No. 11, November 1995, pp 1581-1588
241	Ochs HD, et al., X-linked immunodeficiencies, Curr Allergy Asthma Rep. 2004 Sep;4(4):339-48
242	Okamoto H, et al., Rituximab for rheumatoid arthritis, N Engl J Med. 2004 Oct 28;235(18):1909

EXAMINER	
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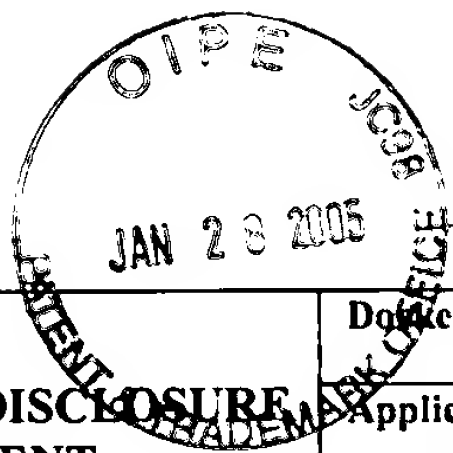
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243	Olsen NJ, et al. A Double-Blind, Placebo-Controlled Study of Anti-CD5 Immunoconjugate in Patients with Rheumatoid Arthritis, Arthritis & Rheumatism, Vol. 39, No. 7, July 1996, pp 1102-1108
244	Oshima SE, Selective signal transduction through the CD3 or CD2 complex is required for class II MHC expression by human T cells, J. Immunol. 1990 Dec 15;145(12):4018-25
245	Ottonello PM, et al., Monoclonal Lym-1 Antibody-Dependent Lysis of B-Lymphoblastoid Tumor Targets by Human Complement and Cytokine-Exposed Mononuclear and Neutrophilic Polymorphonuclear Leukocytes, Blood, Vol 87, No 12, June 15, 1996, pp 5171-5178
246	Panayi GS, T-cell-dependent pathways in rheumatoid arthritis, Current Opinion in Rheumatology 1997; 9:236-240
247	Papadakis KA, et al., Anti-CD20 chimeric monoclonal antibody (rituximab) treatment of immune mediated thrombocytopenia associated with Crohn's disease, Gastroenterology. 2003 Feb;124(2):583
248	Polyak M, et al., Alanine-170 and proline-172 are critical determinants for extracellular CD20 epitopes; heterogeneity in the fine specificity of CD20 monoclonal antibodies is defined by additional requirements imposed by both amino acid sequence and quaternary structure, Blood, 1 May 2002, Volume 99, Number 9
249	Pulczynski S, et al., Antibody-Induced Modulation and Intracellular Transport of CD10 and CD19 Antigens in Human Malignant B-Cell Lines, Leukemia and Lymphoma, 1993, Vol. 15, pp. 243-252
250	Pulczynski S, Antibody-Induced Modulation and Intracellular Transport of CD10 and CD19 Antigens in Human B-Cell Lines: An immunofluorescence and Immunoelectron Microscopy Study, Blood, Vol. 81, No. 6 (March 15), 1993: pp 1549-1557
251	Qian Gong, et al., Importance of Cellular Microenvironmental and Circulatory Dynamics in B Cell Immunotherapy, Journal of Immunology, 2005, 174: 817-826
252	Quinn J, et al., Evan's syndrome complicating multicentric Castleman's disease – dramatic response to rituximab, Eur J Haematol. 2004 Nov;73(5):384-5
253	Reid CD, et al., Identification of hematopoietic progenitors of macrophages and dendritic Langerhans cells (DL-CFU) in human bone marrow and peripheral blood, Blood. 1990 Sep 15;76(6):1139-49
254	Rojas-Garcia R, et al., Chronic neuropathy with IgM anti-ganglioside antibodies: lack of long term response to rituximab, Neurology. 2003 Dec 23;61(12):1814-6
255	Saigal K, et al., Hypocomplementemic urticarial vasculitis with angioedema, a rare presentation of systemic lupus erythematosus: rapid response to rituximab, J Am Acad Dermatol. 2003 Nov;49(5 Suppl):S283-5

EXAMINER	DATE CONSIDERED
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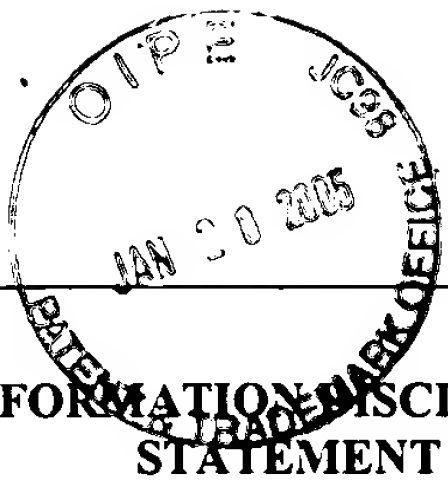
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	Filing Date: July 10, 2000	Group Art Unit: 1636

256	Schadlow MB, et al., Using Rituximab (Anti-CD20 Antibody) in a Patient with Paraneoplastic Pemphigus, J Drugs Dermatol 2003: 2(5); 564-567
257	Schiff C, et al., Autosomal primary Immunodeficiencies affecting human bone marrow B-cell differentiation, Immunol Rev. 2000 Dec; 178:91-8
258	Schiff M, Emerging Treatments for Rheumatoid Arthritis, January 27, 1997, Volume 102, pp 1A-15S
259	Shan D, et al., Constitutive Endocytosis and Degradation of CD22 by Human B Cells, The Journal of Immunology, 1995, 154: 4466-4475
260	Shanafelt TD, et al., Rituximab for immune cytopenia in adults: idiopathic thrombocytopenic purpura, autoimmune hemolytic anemia, and Evans syndrome, Mayo Clin Proc. 2003 Nov;78(11):1340-6
261	Shvidel L, et al., Intractable autoimmune hemolytic anemia B cell chronic lymphocytic leukemia resolved by Rituximab, Leuk Lymphoma. 2004 Jul;45(7):1493-4
262	Siddiqui K, et al., Chronic ataxic neuropathy with cold agglutinins: atypical phenotype and response to anti-CD20 antibodies, Neurology. 2003 Nov 11;61(9):1307-8
263	Tabibzadeh S, et al., Immunoreactivity of human endometrium: correlation with endometrial dating, Fertil Steril. 1990 Oct;55(4):624-31
264	Tedder FT, et al., The B Cell Surface Molecule B1 Is Functionally Linked With B Cell Activation And Differentiation, The Journal of Immunology, Vol. 135, No. 2, August 1985, pp 973-979
265	Todd I, et al. Interferon-gamma induces HLA-DR expression by thyroid epithelium, Clin Exp Immunol. 1985 Aug;61(2):265-73
266	Tsokos GC, B cells, be gone -B-cell depletion in the treatment of rheumatoid arthritis, N Engl J Med. 2004 Jun 17;350(25):2546-8
267	Uchida J, et al., The Innate Mononuclear Phagocyte Network Depletes B Lymphocytes through Fc Receptor-dependent Mechanisms during Anti-Cd20 Antibody Immunotherapy, Journal of Experimental Medicine, Volume 199, Number 12, June 21, 2004, 1659-1669
268	Vaigot P, et al., Detection of distinct subpopulations of Langerhans cells by flow cytometry and sorting, Cytometry, 1985 Sep; 6(5):422-7
269	Virgolini L, et al., Anti-CD20 monoclonal antibody (rituximab) in the treatment in of autoimmune disease. Successful result in refractory Pemphigus vulgaris: report of a case, Haematologica. 2003 Jul;88(7)

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Group Art Unit: 1636

270	Virgolini L, et al., Rituximab in autoimmune disease, Biomed Pharmacother. 2004 Jun;58(5):299-309
271	Webster D, et al., Prompt Response to Rituximab of Severe Hemolytic Anemia With Both Cold and Warm Autoantibodies, American Journal of Hematology, 75:258-259 (2004)
272	Wendling D, et al., A Randomized, Double Blind, Placebo Controlled Multicenter Trial of Murine Anti-CD4 Monoclonal Antibody Therapy in Rheumatoid Arthritis, The Journal of Rheumatology 1998; 25;8; 1458-1461
273	Wicks I, et al., Autologous hemopoietic stem cell transplantation: A possible cure for rheumatoid arthritis?, Arthritis & Rheumatism, Vol. 40, No. 6, June 1997, pp 1005-1011
274	Wylam ME, et al., Succesful treatment of refractory myasthenia gravis using rituximab: a pediatric case report, J Pediatr. 2003 Nov;143(5):674-7
275	Xiao BG, Link H, Antigen-specific T cells in autoimmune diseases with a focus on multiple sclerosis and experimental allergic encephalomyelitis, CMLS, Cell. Mol. Life Sci. 56 (1999) 5-21
276	Yocum DE, T Cells: Pathogenic Cells and Therapeutic Targets in Rheumatoid Arthritis, Seminars in Arthritis and Rheumatism, Vol 29, No 1, August, 1999: pp 27-35
277	Yong VW, Morphologic heterogeneity of human adult astrocytes in culture: correlation with HLA-DR expression, J Neurosci Res. 1990 Dec; 27(4):678-88

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